K061726
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EXHIBIT #1

LIFESTAND
LifeStand "Vivre-Debout"
Rond-point de Rosarge
40, rue Palverne
F 01700 LES ECHETS-FRANCE
Tel : +33(0)4 37 26 27 28
Fax :+33(0)4 37 26 27 29
VAT :FR 23 312 906 613 00079

DEC - 4 2006

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

1. Submitter's Identification:

Lifestand
Rond-point de Rosarge
40, rue Palverne
F 01700 LES ECHETS-FRANCE

Date Summary Prepared: June 12, 2006

2. Name of the Device:
LSC

3. Common or Usual Name:
powered standup wheelchair

4. Device Description:
The LSC is a powered standup wheelchair. It is propelled and steered by varying the speed of the two back wheels. Front castors support the front of the chair and allow indirect steering through the turning back wheels. An electric linear-motor-system puts the seat into a seating or standing position.

Maximum end-user weight	:	120 kg
Wheelchair width	:	67 cm
Wheelchair length	:	87-109 cm
Frame	:	Rigid, in magnesium, epoxy paint
Seat	:	Depth adjustable, with sore proof cushion
Backrest	:	Inclinable. Folds down for transport
Upholstery	:	Polyester fireproof material (M4), washable
Foot-rests	:	Height adjustable
Front wheels	:	Ø 200mm x 50mm, solid
Rear wheels	:	Ø 350mm x 70mm, solid
Brakes	:	automatic electro-magnetic brake and manual standard parking brake
Propulsion	:	electric powered
Elevation	:	electric powered
Rear stabilization	:	Anti-tip wheels (optional).
Idle weight	:	94,7kg

5. Intended Use:

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The LSC offers electrically operated seated and standing mobility to users with ambulatory impairments, including people with spinal cord injury, spina bifibia, cerebral palsy, multiple sclerosis, muscular dystrophy, polio, rheumatism, etc.

6. **Comparison to Predicate Devices:**
The LSC is substantially equivalent to its forerunner model LSC Compact by Lifestand, K041535 and the standup wheelchair LCM by LEVO, K963817

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**
To approve the performance of the LSC, tests according to current applicable standards where performed at test-laboratories of European notified bodies:

EN 12182: 1999	Technical aids for disabled persons. General requirements and test methods
EN 12184: 1999	Electrically powered wheelchairs, scooters and their chargers -requirements and test methods
ISO 7176-1: 1999	Wheelchairs. Determination of static stability
ISO 7176-2: 2001	Wheelchairs. Determination of dynamic stability of electric wheelchairs
ISO 7176-3: 1988	Wheelchairs. Determination of effectiveness of brakes
ISO 7176-4: 1997	Wheelchairs. Energy consumption of electric wheelchairs and scooters for determination of theoretical distance
ISO 7176-5: 1986	Wheelchair tests. Methods for determination of overall dimensions, mass and turning space
ISO 7176-6: 2001	Wheelchairs. Determination of maximum speed, acceleration and deceleration of electric wheelchairs
ISO 7176-7: 1998	Wheelchairs. Measurement of seating and wheel dimension
ISO 7176-8: 1998	Wheelchairs. Requirements and test methods for static, impact and fatigue strength
ISO 7176-9: 2001	Wheelchairs. Climatic test for electric wheelchairs
ISO 7176-10: 1988	Wheelchairs. Determination of obstacle-climbing ability of electric wheelchairs
ISO 7176-14: 1997	Power and Control systems for electric wheelchairs – Requirements and test methods
ISO 7176-15: 1996	Wheelchairs. Requirements for information disclosure, documentation and labeling
ISO 7176-16: 1997	Wheelchairs - Part 16: Resistance to ignition of upholstered parts - Requirements and test methods
ISO 7176-20: 2001	Wheelchairs. Determination of the performance of stand-up type wheelchairs
ISO 7176-21: 2003	Wheelchairs. Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and motorized scooters
EN ISO 10993-1: 2003	Biological evaluation of medical devices. Evaluation and testing

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EN ISO 10993-5: 1999	Biological evaluation of medical devices. Tests for in vitro cytotoxicity

8. Discussion of Clinical Tests Performed:

Clinical tests were not performed

9. Conclusions:

Lifestand believes that the LSC is substantially equivalent to the predicate and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 2006

LifeStand "Vivre-Debout"
% Ms. Stefanie D. Bankston
Rond-point de Rosarge
40, rue Palverne
F 01700 Les Echets- France

Re: K061726
Trade/Device Name: LSC
Regulation Number: 21 CFR 890.3900
Regulation Name: Standup wheelchair
Regulatory Class: Class II
Product Code: IPL
Dated: November 20, 2006
Received: November 28, 2006

Dear Ms. Bankston:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

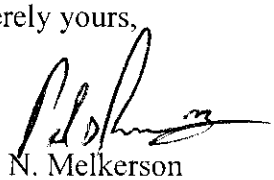
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit #3

510(k) Number (if known): K061726

Device Name: LSC

Indications For Use:

The LSC offers electrically powered seated and standing mobility to users with ambulatory impairments, including people with spinal cord injury, spina bifida, cerebral palsy, multiple sclerosis, muscular dystrophy, polio, rheumatism, etc.

Prescription Use X (Per 21 CFR 801 Subpart D) OR Over-The Counter Use (21 CFT 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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